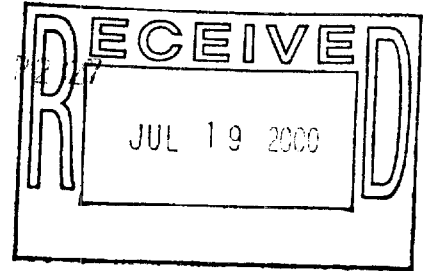




0695 '00 AUG -8



June 29, 2000

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Rumapiex is a special combination supplement formulated to support the bone-joint complex and related structures that are subject to repetitive use and marked by chronic, systemic responses to repetitive use.
- (2) The calcium in Rumaplex helps protect against bone loss and support bone health.

These statements are made for a dietary supplement containing a proprietary blend of nutritional yeast, bovine brain, magnesium citrate, dried buckwheat (leaf) juice, buckwheat (seed), veal bone PMG™ extract, dried pea (vine) juice, betaine hydrochloride, bovine adrenal, soy (bean), bovine prostate Cytosol™ extract, defatted wheat (germ), oat flour, carrot (root), veal bone, bovine liver PMG™ extract, bovine spleen, ovine spleen, bovine liver, licorice (root), dried beet (leaf) juice, peanut (bran), manganese glycerophosphate, enzymatically processed *Tillandsia usneoides* and beet (root). Other ingredients include gelatin, calcium lactate, calcium glycerophosphate, water, potassium citrate, calcium stearate, natural colors, niacinamide, ascorbic acid, and vitamin A palmitate. The name of the product is Rumaplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.  
975-0162

LE+ 5650  
71575

